DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 26, 2014

Suzhou Xixin Medical Instruments Co., Ltd.
% Mike Gu
Regulatory Manager
Osmunda Medical Device Consulting Co., Ltd.
No. 982 Cogyun Road
7th Fl. Jinggui Business Bldg
Baiyun District
Guangzhou, Guangdong, 510420 CN

Re: K131817
Trade/Device Name: Extracorporeal Shock Wave Lithotripter
Regulation Number: 21 CFR§ 876.5990
Regulation Name: Extracorporeal Shock Wave Lithotripter
Regulatory Class: II
Product Code: LNS
Dated: June 18, 2013
Received: June 25, 2013

Dear Mike Gu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K131817

Device Name: Extracorporeal Shock Wave Lithotripter

Indications for Use: CS-2012A-3 is intended for use by attending physician in the treatment of all kinds of calculi in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Prescription Use _X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k)_____

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	June 15, 2013
Submitter:	Suzhou Xixin Medical Instruments Co. Ltd
Primary Contact Person:	Mike Gu Regulatory Affairs Manager Guangzhou Osmunda Medical Device Consulting Co., Ltd Tel: +86-20-62321333 Fax: +86-20-86330253
Secondary Contact Person:	Du JunYuan General Manager Suzhou Xixin Medical Instruments Co. Ltd Tel: +86-512-65270692/ 65287789 Fax:+86-512-65278410 Add: No.28, Fengjin Road, Wuzhong District, Suzhou, 215128, P.R. China
Device: Trade Name:	Extracorporeal Shock Wave Lithotripter
Common/Usual Name:	Extracorporeal Shock Wave Lithotripter
Classification Names:	According to 21 CFR §876.5990, FDA has classified extracorporeal shock wave lithotripter as Class II device with special controls. The Product Code for this lithotripter is 78 LNS.
Product Code:	78 LNS
Predicate Device(s):	P840008/S065; K103217
Device Description:	ESWL, model CS-2012A-3, is an mobile electromagnetic lithotripter with a focal zone to treat patients, the shock wave generator has a high voltage power supply, a closed circuit water supply system with a tank, an spherical concave electromagnetic coil, a membrane and a water cushion (rubber membrane) for the acoustic conductivity of the shock waves to the patient. It is intended to be used properly by trained and qualified medical personnel for use in noninvasive fragmentation of urinary calculi in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter). The shock waves are generated by the high voltage discharge through the electromagnetic coil which repels the membrane creating a shockwave. The shockwave is then focused to the focal point. The stones to be fragmented are positioned at this focal point by moving the motorized patient table in 3 axis. The localization is performed with a separate and commercially

	available mobile fluoroscopic x-ray unit and/or US equipment. The device includes following parts: 1. ESWL device The ESWL device contains therapy head, main switch, control panel, target indicator and foot pedal. It also provides patient with treatment, controls functions of CS-2012A-3. 2. Therapy table Therapy table consists of table (For personal hygiene, the table should be covered by disposable medical nonwoven fabrics in treatment), table supporter and 3-dimension movement. Patient is positioned on therapy table. Table cutout area allows positioning of therapy table near patient, table can be moved as required. Table motion is completely independent of ESWL device. It has its own 3 dimension movement, not to link CS-2012A-3.
Intended Use:	CS-2012A-3 is intended for use by attending physician in the treatment of all kinds of calculi in the kidney (renal pelvis and renal calyces) and ureter (upper, middle, and lower ureter).

Technology:

ESWL model CS-2012A-3 is a mobile electromagnetic lithotripter, it generates shock waves by means of electromagnetic shock wave generator which consists of a spherical concave coil and metallic membrane, invented by Prof. Eisenmenger. The predicate device from Dornier uses the same technology from the design and energy source.

The shock waves are generated by the high voltage discharge through the electromagnetic coil which repels the membrane creating a shockwave. The shock wave focuses automatically via the structure of spherical concave of coil during its propagation. The stones to be fragmented are positioned at this focal point by moving the motorized patient table in 3 axis. The localization is performed with a separate and commercially available mobile fluoroscopic x-ray unit and/or US equipment.

The calculus to be treated is positioned and fragmented in the focal point of the shock wave.

The shock wave characteristics are reported below by taking the guideline described in the consensus standard IEC 61846 "Ultrasonics - Pressure pulse lithotripters - Characteristics of fields" (1998) into consideration. The hydrophones are used in the measurements.
The details of the measurements/calculations are given in relevant part of 510(k) application.

The results are found similar to the predicate device characteristics.

Parameter	Min 7.0kV	Typical 9.3Kv	Maximum 10.5Kv
Peak-positive acoustic pressure p+:	7.6MPa	27.4MPa	39.8MPa
Peak-negative acoustic pressure p_:	-3MPa	-4.1MPa	-4MPa
Compressional pulse duration tFWHMp+:	1.305 μ s	428.8ns	409.5ns
Rise time (10%-90%)	1.14 μ s	452ns	216ns

	tr:			
	Total derived pulse-intensity integral PIIT:	45.8J/m2	196.4J/m2	494.4J/m2
	Positive derived pulse-intensity integral PIIP:	33.0J/m2	177.3J/m2	469.3J/m2
	Distance focus position – target location in z-direction:	-16mm	-9.5mm	+7mm
	Z1	76 mm	57 mm	69 mm
	Z2	44 mm	38 mm	55 mm
	Z3	16 mm	9.5 mm	7 mm
	Distance focus position – target location in x-direction:	0mm	0mm	0mm
	Distance focus position – target location in y-direction:	0mm	0mm	0mm
	Focal extent (in z-direction) fz:	120mm	95mm	124mm
	Maximum focal width (in x-direction) fx:	15mm	9.5mm	10mm
	Orthogonal focal width (in y-direction) fy:	14mm	8.5mm	8.5mm
	Focal cross-sectional area Af:	1.65cm2	0.63cm2	0.67cm2
	Focal volume Vf:	13.2cm3	4.0cm3	5.5cm3
	Total derived focal acoustic pulse energy	5.7mJ	10.0mJ	22.7mJ

	EfT:			
	Total derived acoustic pulse energy ERT (R=5mm):	3.1mJ	12.1mJ	27.1mJ
	Positive derived focal acoustic pulse energy EfP:	4.1mJ	8.9mJ	21.1mJ
	Positive derived acoustic pulse energy ERP (R=5mm):	2.2mJ	10.9mJ	25.5mJ

Determination of Substantial Equivalence:

Summary of non-Clinical Tests:

The Extracorporeal Shock Wave Lithotripter was designed and tested for compliance to the following standards:

a. IEC 60601-2-36, "Medical electrical equipment – Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy" (1997);
b. IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995;
c. IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests;
d. ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process;
e. ISO 10993-5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
f. ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

The product specifications had been tested as attachment 1:

Attachment 1:

Voltage/Frequency	ESWL Module	110V, 60Hz
Power Supply	ESWL Module	1.0 kVA
Max. Load of The	Weight of	Max. 136kg

	Therapy Table	patient	
	Physical Parameters of Shock Wave in Focus Area.		Pmax: 5～50MPa
			P_:-2～-8MPa
			DX，DY: -2～+2mm
			DZ: -20～+20mm
			Tw:0.2～2 μs
			Tr:0.1～2 μs
			ϕfocus≈15mm
	Lifetime of coil		≥10^6 shots

Summary of Clinical Tests:

According to the "Guidance for the Content of Premarket Notifications for Extracorporeal Shock Wave Lithotripters Indicated for the Fragmentation of Kidney and Ureteral Calculi" section 8.D clinical performance testing, the clinical investigations were performed at 2 sites with 1 and 2 weeks follow-up to support this application. Totally 144 (105 male, and 39 female) patients with stones were treated. The stones sizes treated were not more than 20 mm. None of the patients received general anesthesia. The overall success rate of the investigations is measured as 80%.

The experiences of physicians have shown that patients treated by the CS-2012A-3 are safe and having high evaluations for the device function. And the user's manual is adequate for the operation of CS-2012A-3. The incidence of device malfunction does not happen in these clinical investigations.

ESWL demonstrates with a confirmatory clinical study that it is performed as the substantial equivalence, please see appendix C1, appendix C2, appendix C3, appendix C4 and appendix C5 .

Conclusion:	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the extracorporeal shock wave lithotripter, model CS-2012A-3 from Suzhou Xixin Medical Instruments Co. Ltd is as safe, as effective, and performs at least as safely and effectively as the legally marketed device identified in paragraph(3) of this section.